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EXAMINER

GIBBS, TERRA C

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/980,265

Applicant(s)

BACHY ET AL.

Examiner

Terra C. Gibbs

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 19-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office Action is a response to Applicants Amendment and Remarks filed October 22, 2003. Claims 1, 6, 8, 19, and 20 have been amended. Claims 1-14 and 19-21 are pending.

Claims 1-14 and 19-21 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Arguments***

Applicants Amendment filed December 18, 2003 to comply with the sequence rules is acknowledged. Applicants Amendment filed April 6, 2005 to comply with 37 CFR 1.121 is acknowledged.

### ***Priority***

It is noted that the instant application is a 371 of PCT/FROO/01566. PCT/FROO/01566 claims benefit of foreign application 99/07457, filed June 8, 1999. However the instant claims have not been afforded priority back to June 8, 1999 because support cannot be found for the new limitation "in which N<sub>1</sub> and N<sub>2</sub> are not both thymines". Specifically, the instant claims have been amended and are drawn to an immunostimulant oligonucleotide comprising 5'-TTN<sub>1</sub>N<sub>2</sub>TT-3', wherein T signifies

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thymine,  $N_1$  and  $N_2$  are adenine, thymine, cytosine, or guanine, in which  $N_1$  and  $N_2$  are not both thymines, and wherein the oligonucleotide lacks a dinucleotide CG in which the cytosine C is not methylated. The Examiner cannot find support for the new limitation "in which  $N_1$  and  $N_2$  are not both thymines" in foreign application 99/07457, filed June 8, 1999.

In summary, since support cannot be found in foreign application 99/07457 for the new limitation, "in which  $N_1$  and  $N_2$  are not both thymines", the instant application has been given priority to the filing date of the instant application, which is March 22, 2002.

### ***Specification***

In the previous Office Action mailed April 23, 2003, the specification was objected to because it made reference to Figures 1-11, where Figures 1-11 could not be found. **This objection is withdrawn** in view of Applicants amendment filed October 22, 2003 to remove the text referring to Figures 1-11 from the specification.

### ***Claim Rejections - 35 USC § 101***

In the previous Office Action mailed April 23, 2003, claim 19 was rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a

claim which is not a proper process claim under 35 U.S.C. 101. **This rejection is withdrawn** in view of Applicants Amendment to claim 19 filed October 22, 2003.

***Claim Rejections - 35 USC § 112***

In the previous Office Action mailed April 23, 2003, claims 19, 6 and 7 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This rejection is withdrawn** in view of Applicants Amendment to the claims filed October 22, 2003.

In the previous Office Action mailed April 23, 2003, claims 20 and 21 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **This rejection is withdrawn** in view of Applicant's Remarks. Specifically, the Examiner is withdrawing this rejection because the antisense art used to support this enablement rejection was inappropriate and because it is well known in the art that immunostimulant oligonucleotides have therapeutic applications in mammals as evidenced by Davis et al. (Journal of Immunology, 1998 Vol. 160:870-876), Hartmann et al. (Journal of Immunology, 2000 Vol. 164:1617-1624), Krieg et al. (Pharmacology and Therapeutics, 1999 Vol. 84:113-120) and Klinman et al. (Vaccine, 1999 Vol. 17:19-25).

***Claim Rejections - 35 USC § 102***

In the previous Office Action mailed April 23, 2003, claims 1, 2, 9, 10 and 19 were rejected under 35 U.S.C. 102(b) as being anticipated by Hutcherson et al. [WO 95/26204]. **This rejection is withdrawn** in view of Applicants arguments. Specifically, the Examiner agrees that SEQ ID NO:1 taught by Hutcherson et al. has a dinucleotide CG in which the cytosine is not methylated.

In the previous Office Action mailed April 23, 2003, claims 1, 2, 9, 10 and 12 were rejected under 35 U.S.C. 102(b) as being anticipated by Parronchi et al. (Journal of Immunology, 1999 Vol. 163:5946-5953). **This rejection is withdrawn** in view of the fact that the oligonucleotide taught by Parronchi et al. contains a dinucleotide CG in which the cytosine is not methylated (see oligonucleotide 2105 at Table 1).

It is noted that in response to this rejection, Applicants argued that Parronchi et al. does not qualify as prior art against the instant application since the priority date of the instant application is June 8, 1999. This was not found persuasive by the Examiner because the instant application does not have a priority date of June 8, 1999, but instead has a priority date of March 22, 2002 as discussed above in the section labeled "Priority" on page 2.

In the previous Office Action mailed April 23, 2003, claims 1-8, 9, 13, 14 and 19 were rejected under 35 U.S.C. 102(b) as being anticipated by Liang et al. (Journal of Clinical Investigation, 1996 Vol. 98:1119-1129). **This rejection is withdrawn** in view of Applicants arguments. Specifically, the Examiner is withdrawing this rejection against

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oligonucleotide 2105 of Liang et al. in view of Applicants arguments that oligonucleotide 2105 contains a dinucleotide CG in which the cytosine C is not methylated. The Examiner is withdrawing this rejection against DSP28, DSP39, and DSP40 of Liang et al. in view of Applicants amendment to the claims to recite, "in which N<sub>1</sub> and N<sub>2</sub> are not both thymines". The Examiner is withdrawing this rejection against DSP19 of Liang et al. in view of Applicants arguments that DSP19 defines a genus of oligonucleotides and a genus does not anticipate a species unless the genus clearly names the claimed species or one of ordinary skill in the art can "at once envisage" the species within the genus.

In the previous Office Action mailed April 23, 2003, claims 1-3 were rejected under 35 U.S.C. 102(b) as being anticipated by Lang et al. (European Journal of Immunology, 1999 Vol. 29:3496-3506). **This rejection is maintained** for the reasons of record set forth in the Office Action mailed March 23, 2003.

In response to this rejection, Applicants argued that Lang et al. does not qualify as prior art against the instant application since the priority date of the instant application is June 8, 1999. This was not found persuasive by the Examiner because the instant application does not have a priority date of June 8, 1999, but instead has a priority date of March 22, 2002 as discussed above in the section labeled "Priority" on page 2. In this regard, Lang et al. clearly anticipate claims 1-3 because Lang et al. disclose a guanosine-rich oligonucleotide comprising the formula 5'-TTN<sub>1</sub>N<sub>2</sub>TT-3', wherein T signifies thymine, N<sub>1</sub> and N<sub>2</sub> in which N<sub>1</sub> and N<sub>2</sub> are not both thymines, and in

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which N<sub>1</sub> and N<sub>2</sub> are adenine and guanine, respectively, and wherein the oligonucleotide lacks a dinucleotide CG in which the cytosine C is not methylated (see page 3501, Table 2: oligonucleotide GR1BC).

It is noted that Lang et al. also anticipate claims 9-14. Claims 9-14 are dependent on claim 1, drawn to an immunostimulant oligonucleotide comprising 5'-TTN<sub>1</sub>N<sub>2</sub>TT-3', wherein T signifies thymine, N<sub>1</sub> and N<sub>2</sub> are adenine, thymine, cytosine, or guanine, in which N<sub>1</sub> and N<sub>2</sub> are not both thymines, and wherein the oligonucleotide lacks a dinucleotide CG in which the cytosine C is not methylated, with the further limitations, wherein the oligonucleotide induces lymphocyte proliferation, specific cytokine secretion, and activation of specific markers.

The guanosine-rich oligonucleotide disclosed by Lang et al. meets the structural limitations of the claimed invention and would be expected to function as an immunostimulant oligonucleotide, absent evidence to the contrary.

The burden of establishing whether the prior art guanosine-rich oligonucleotide has the further function of inducing lymphocyte proliferation, specific cytokine secretion, and activation of specific markers falls to Applicant. See MPEP 2112.01, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709,



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15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433." See also MPEP 2112: "[T]he PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2112 citing *In re Fitzgerald* 205 USPQ 594, 596, (CCPA 1980), quoting In re Best 195 USPQ 430 as per above. Therefore, it falls to Applicant to determine and provide evidence that the guanosine-rich oligonucleotide disclosed by Lang et al. would or would not have the additional functional limitation of inducing lymphocyte proliferation, specific cytokine secretion, and activation of specific markers as claimed.

Therefore, absent evidence to the contrary, Lang et al. anticipate claims 1-3 and 9-14.

After careful reconsideration of the claims, a new grounds of rejection is presented below:

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 and 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Sanchez-Pescador et al. [U.S. Patent No. 5,618,674].

Claim 1 is drawn to an immunostimulant oligonucleotide comprising 5'-TTN<sub>1</sub>N<sub>2</sub>TT-3', wherein T signifies thymine, N<sub>1</sub> and N<sub>2</sub> are adenine, thymine, cytosine, or guanine, in which N<sub>1</sub> and N<sub>2</sub> are not both thymines, and wherein the oligonucleotide lacks a dinucleotide CG in which the cytosine C is not methylated. Claims 2-5 and 9-14 are dependent on claim 1 and include all the limitations of claim 1 with the further limitations, wherein 5'-TTN<sub>1</sub>N<sub>2</sub>TT-3' is repeated once, wherein 5'-TTN<sub>1</sub>N<sub>2</sub>TT-3' is repeated twice, wherein the oligonucleotide comprises from 6 to 100 nucleotides, wherein N<sub>1</sub> and N<sub>2</sub> represents adenine and guanine, respectively, and wherein the oligonucleotide induces lymphocyte proliferation, specific cytokine secretion, and activation of specific markers.

Sanchez-Pescador et al. disclose an amplifier probe with the following sequence:  
5'-TTCTTTAGATTTCTTAGTTATTTCTTCAA-3' (see SEQ ID NO:5).

The amplifier probe disclosed by Sanchez-Pescador et al. meets the structural limitations of the claimed invention and would be expected to function as an immunostimulant oligonucleotide, absent evidence to the contrary.

The burden of establishing whether the prior art amplifier probe has the further function of inducing lymphocyte proliferation, specific cytokine secretion, and activation of specific markers falls to Applicant. See MPEP 2112.01, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433." See also MPEP 2112: "[T]he PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2112 citing *In re Fitzgerald* 205 USPQ 594, 596, (CCPA 1980), quoting *In re Best* 195 USPQ 430 as per above. Therefore, it falls to Applicant to determine and provide evidence that the amplifier probe disclosed by Sanchez-Pescador et al. would or would not have the additional functional limitation of inducing lymphocyte proliferation, specific cytokine secretion, and activation of specific markers as claimed.

Therefore, absent evidence to the contrary, Sanchez-Pescador et al. anticipate claims 1-5 and 9-14.

Claims 1-4 and 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Meyer et al. [U.S. Patent No. 5,574,142].

Meyer et al. disclose an oligonucleotide peptide linker with the following sequence: 5'-TAATTATTCAGCCATTTTATTATTAGTT-3' (see SEQ ID NO:9).

The oligonucleotide peptide linker disclosed by Meyer et al. meets the structural limitations of the claimed invention and would be expected to function as an immunostimulant oligonucleotide, absent evidence to the contrary.

The burden of establishing whether the prior art oligonucleotide peptide linker has the further function of inducing lymphocyte proliferation, specific cytokine secretion, and activation of specific markers falls to Applicant. See MPEP 2112.01, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433." See also MPEP 2112: "[T]he PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2112 citing *In re Fitzgerald* 205 USPQ 594, 596, (CCPA 1980),

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quoting *In re Best* 195 USPQ 430 as per above. Therefore, it falls to Applicant to determine and provide evidence that the oligonucleotide peptide linker disclosed by Meyer et al. would or would not have the additional functional limitation of inducing lymphocyte proliferation, specific cytokine secretion, and activation of specific markers as claimed.

Therefore, absent evidence to the contrary, Meyer et al. anticipate claims 1-4 and 9-14.

Claims 1-3 and 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Herman, J. [WO 97/46705].

Herman discloses an unmethylated BRCA2 primer with the following sequence: 5'-TGGTTTTTGTTTAGTTTATTTTGG-3' (see SEQ ID NO:88).

The unmethylated BRCA2 primer disclosed by Herman meets the structural limitations of the claimed invention and would be expected to function as an immunostimulant oligonucleotide, absent evidence to the contrary.

The burden of establishing whether the prior art BRCA primer has the further function of inducing lymphocyte proliferation, specific cytokine secretion, and activation of specific markers falls to Applicant. See MPEP 2112.01, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that

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the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433." See also MPEP 2112: "[T]he PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2112 citing *In re Fitzgerald* 205 USPQ 594. 596, (CCPA 1980), quoting In re Best 195 USPQ 430 as per above. Therefore, it falls to Applicant to determine and provide evidence that the BRCA primer disclosed by Herman would or would not have the additional functional limitation of inducing lymphocyte proliferation, specific cytokine secretion, and activation of specific markers as claimed.

Therefore, absent evidence to the contrary, Herman anticipates claims 1-3 and 9-14.

Claims 1-3 and 9-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Gonzalgo et al. [U.S. Patent No. 6,251,594].

Gonzalgo et al. disclose a PCR primer with the following sequence:

5'- GTAGGTGGGGAGGAGTTTAGTT-3' (see SEQ ID NO:13).

The PCR primer disclosed by Gonzalgo et al. meets the structural limitations of the claimed invention and would be expected to function as an immunostimulant oligonucleotide, absent evidence to the contrary.

The burden of establishing whether the prior art PCR primer has the further function of inducing lymphocyte proliferation, specific cytokine secretion, and activation of specific markers falls to Applicant. See MPEP 2112.01, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433." See also MPEP 2112: "[T]he PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2112 citing *In re Fitzgerald* 205 USPQ 594, 596, (CCPA 1980), quoting *In re Best* 195 USPQ 430 as per above. Therefore, it falls to Applicant to determine and provide evidence that the PCR primer disclosed by Gonzalgo et al. would or would not have the additional functional limitation of inducing lymphocyte proliferation, specific cytokine secretion, and activation of specific markers as claimed.

Therefore, absent evidence to the contrary, Gonzalgo et al. anticipate claims 1-3 and 9-14.

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Applicant's amendment necessitated the new ground(s) of rejection presented below:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 and 19-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1-14 and 19-21 are drawn to an immunostimulant oligonucleotide comprising 5'-TT N<sub>1</sub>N<sub>2</sub>TT-3', wherein T signifies thymine, N<sub>1</sub> and N<sub>2</sub> are adenine, thymine, cytosine, or guanine, in which N<sub>1</sub> and N<sub>2</sub> are not both thymines, and wherein the oligonucleotide lacks a dinucleotide CG in which the cytosine C is not methylated and methods of using said immunostimulant oligonucleotide.

Claim 1 has been amended to include the limitation, "in which N<sub>1</sub> and N<sub>2</sub> are not both thymines". This new limitation appears to be new matter. Additionally, claim 6 have been amended to include the limitation, "wherein when there are more than two units, each N<sub>3</sub> nucleotide". This new limitation appears to be new matter.



In the response filed October 23, 2003, Applicants indicate that support for the claim amendments can be found in the specification as originally filed. The specification as originally filed recites, "N<sub>1</sub> and N<sub>2</sub> may each represent adenine, thymine, cytosine, or guanine" (see page 2, lines 29 and 30; page 4, lines 16-17 and lines 24-25; and page 7, lines 2 and 3, for example). However, the specification as originally filed does not appear to support the new limitation, "in which N<sub>1</sub> and N<sub>2</sub> are not both thymines". The specification as originally filed recites, "units are separated by a nucleotide N<sub>3</sub> which, each time, may be identical or different" (see page 3, lines 19 and 20; and page 8, lines 4 and 5). However, the specification as originally filed does not appear to support the new limitation "wherein when there are more than two units, each N<sub>3</sub> nucleotide".

Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP § 2163.06 which states, when filing an amendment, an applicant should show support in the original disclosure for new or amended claims (See MPEP § 714.02 and § 2163.06).

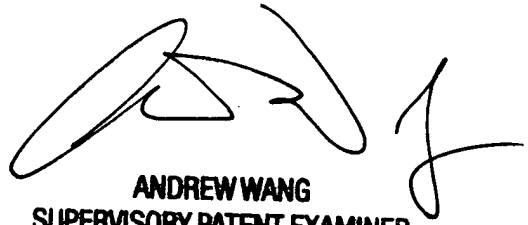
Applicant is required to cancel the new matter in the reply to this Office Action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wang Andrew can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tcg  
June 29, 2005



**ANDREW WANG**  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600